

IN THE CLAIMS

This listing of claims will replace all prior versions and listing of claims in the application. The following amendments are without prejudice and do not constitute an admission regarding the patentability of the amended subject matter and should not be so construed.

Claims 1 – 150. (Canceled).

Claim 151. (Currently Amended) An orally deliverable pharmaceutical composition, comprising: about 1 mg to about 100 mg omeprazole, at least a portion of which is not enteric coated, in a therapeutically effective amount and sodium bicarbonate, wherein:

- (a) the composition is in a form of a solid dosage form [[unit]];
- (b) the composition comprises no aluminum glycinate, no aluminum hydroxide-sodium bicarbonate co-precipitate and no sucralfate; and
- (c) upon oral administration of the composition to a group of subjects, the subjects exhibit an average plasma concentration of the omeprazole ~~proton pump inhibitor~~ of at least about 0.1 µg/ml at any time within about 30 minutes after administration.

Claim 152. (Currently Amended) The composition of claim 151, wherein the dosage form [[unit]] is selected from the group consisting of a tablet, a capsule, a powder, a suspension tablet, a chewable tablet, an effervescent tablet, a troche and a lozenge.

Claim 153. (Currently Amended) The composition of claim 151, wherein the dosage form [[unit]] is selected from the group consisting of a chewable tablet and a capsule.

Claim 154. (Previously Presented) The composition of claim 151, wherein at least a portion of the omeprazole is enteric coated.

Claim 155. (Canceled)

Claim 156. (Currently Amended) The composition of claim 151, wherein the omeprazole is present in the composition in an amount of about 1 mg to about 80 [[1000]] mg.

Claim 157. (Currently Amended) The composition of claim 151, wherein the omeprazole is present in the composition in an amount of about 5 mg to about 100 [[300]] mg.

Claim 158. (Previously Presented) The composition of claim 151, wherein the omeprazole is present in the composition in an amount of about 10 mg to about 100 mg.

Claim 159. (Currently Amended) The composition of claim 151, wherein the omeprazole is present in the composition in an amount of about 2 mg, about 5 mg, about 10 mg, about 15

mg, about 20 mg, about 25 mg, about 30 mg, about 40 mg, about 50 mg, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg[[.]] or about 100 mg, ~~about 105 mg, about 110mg, about 115 mg, about 120 mg, about 150 mg, about 200 mg, about 250 mg, or about 300 mg.~~

Claim 160. (Canceled)

Claim 161. (Canceled)

Claim 162. (Canceled)

Claim 163. (Previously Presented) The composition of claim 151, further comprising at least one pharmaceutically acceptable excipient selected from the group consisting of a carrier, a binder, a suspending agent, a flavoring agent, a sweetening agent, a disintegrant, a flow aid, a lubricant, an adjuvant, a colorant, a diluent, a moistening agent, a preservative, a parietal cell activator, an anti-foaming agent, an antioxidant, a chelating agent, an antifungal agent, an antibacterial agent, an isotonic agent, and mixtures thereof.

Claim 164. (Canceled)

Claim 165. (Currently Amended) The composition of claim 151, further ~~comprising~~ comprising at least one additional buffering agent selected from the group consisting of potassium bicarbonate, magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, magnesium silicate, magnesium citrate, aluminum hydroxide, aluminum hydroxide/magnesium carbonate, potassium carbonate, potassium citrate, ~~aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum glycinate,~~ aluminum magnesium hydroxide, sodium citrate, sodium tartrate, sodium acetate, sodium carbonate, sodium polyphosphate, potassium polyphosphate, sodium pyrophosphate, potassium pyrophosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium phosphate, tripotassium phosphate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium hydroxide, calcium lactate, calcium carbonate, calcium gluconate, calcium bicarbonate, calcium citrate, potassium phosphate, sodium phosphate, and mixtures thereof.

Claim 166. (Previously Presented) The composition of claim 151, wherein the sodium bicarbonate is present in the composition in a total amount of about 1 mEq to about 200 mEq.

Claim 167. (Previously Presented) The composition of claim 151, wherein the sodium bicarbonate is present in the composition in a total amount of about 3 mEq to about 45 mEq.

Claim 168. (Previously Presented) The composition of claim 151, wherein the sodium bicarbonate is present in the composition in a total amount of about 4 mEq to about 100 mEq.

Claim 169. (Previously Presented) The composition of claim 151, wherein the sodium bicarbonate is present in the composition in a total amount of about 4 mEq to about 30 mEq.

Claim 170. (Previously Presented) The composition of claim 151, wherein the sodium bicarbonate is present in the composition in a total amount of about 10 mEq to about 70 mEq.

Claim 171. (Canceled)

Claim 172. (Previously Presented) The composition of claim 151, wherein the sodium bicarbonate is present in the composition in a total amount of about 250 mg to about 4000 mg.

Claim 173. (Previously Presented) The composition of claim 151, wherein the sodium bicarbonate is present in the composition in a total amount of about 1000 mg to about 1680 mg.

Claim 174. (Previously Presented) The composition of claim 151, wherein the sodium bicarbonate is present in the composition in a total amount of about 7 mEq to about 25 mEq.

Claim 175. (Previously Presented) The composition of claim 151, wherein the omeprazole is present in the composition in an amount of about 20 mg.

Claim 176. (Previously Presented) The composition of claim 151, omeprazole is present in the composition in an amount of about 40 mg.

Claim 177. (Previously Presented) The composition of claim 151, further comprising magnesium hydroxide.

Claim 178. (Previously Presented) The composition of claim 177, wherein the magnesium hydroxide is present in the composition in a total amount of about 12 mEq to about 24 mEq.

Claim 179. (Canceled)

Claim 180. (Previously Presented) The composition of claim 151, further comprising calcium carbonate.

Claim 181. (Canceled)

Claim 182. (Previously Presented) The composition of claim 151, wherein at least a portion of the omeprazole is micronized.

Claim 183. (Previously Presented) The composition of claim 151, wherein at least a portion of the sodium bicarbonate is micronized.

Claim 184. (Currently Amended) The composition of claim 151, wherein the solid dosage form [[unit]] is non-enteric coated.

Claim 185. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of at least about 0.1 µg/ml at any time within about 20 minutes after administration.

Claim 186. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of at least about 0.1 µg/ml at any time within about 15 minutes after administration.

Claim 187. (Currently Amended) The composition of claim 151, wherein the solid dosage form [[unit]] is a chewable tablet and wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of at least about 0.1 µg/ml at any time within about 10 minutes after administration.

Claim 188. (Currently Amended) The composition of claim 151, wherein the solid dosage form [[unit]] is a chewable tablet and wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of at least about 0.2 µg/ml at any time within about 15 minutes after administration.

Claim 189. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of at least about 0.1 µg/ml maintained from at latest about 15 minutes after administration to at earliest about 6 hours after administration.

Claim 190. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of at least about 0.15 µg/ml maintained from at latest about 15 minutes after administration to at earliest about 1.5 hours after administration.

Claim 191. (Currently Amended) An orally deliverable pharmaceutical composition, comprising: about 1 mg to about 100 mg omeprazole or an enantiomer, isomer, tautomer,

~~prodrug, free base, or salt thereof, at least a portion of which is not enteric coated, in a therapeutically effective amount~~ and about 5 mEq to about 70 mEq sodium bicarbonate, wherein:

- (a) the composition is in a form of a chewable tablet or capsule; and
- (b) the composition comprises no aluminum glycinate, no aluminum hydroxide-sodium bicarbonate co-precipitate and no sucralfate; and
- (c) upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of at least about 0.1 µg/ml at any time within about 30 minutes after administration.

Claim 192. (Previously Presented) The composition of claim 191, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mg to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of at least about 0.7 µg/ml within about 30 minutes after administration.

Claim 193. (Currently Amended) The composition of claim 191, wherein the solid dosage form [[unit]] is a chewable tablet and wherein upon oral administration of the composition group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of at least about 0.1 µg/ml at any time within about 15 minutes after administration.

Claim 194. (Previously Presented) The composition of claim 191, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mg to a group of fasted adult human subjects, the subjects exhibit an average C_{max} of the omeprazole of at least about 1.0 µg/ml.

Claim 195. (Currently Amended) The composition of claim 191, wherein the solid dosage form [[unit]] is a chewable tablet and wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mg to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of at least about 0.2 µg/ml at any time within about 15 minutes after administration.

Claim 196. (Previously Presented) The composition of claim 191, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mg to a group of fasted adult human subjects, the subjects exhibit an average T_{max} of about 15 minutes to about 1 hour.

Claim 197. (Previously Presented) The composition of claim 191, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mg to a group of fasted adult human subjects, the subjects exhibit a T_{\max} within about 45 minutes after administration.

Claim 198. (Currently Amended) The composition of claim 191, wherein the dosage form [[unit]] is a capsule.

Claim 199. (Currently Amended) The composition of claim 191, wherein the dosage form [[unit]] is a chewable tablet.

Claim 200. (Previously Presented) The composition of claim 191, further comprising at least one pharmaceutically acceptable excipient selected from the group consisting of a carrier, a binder, a suspending agent, a flavoring agent, a sweetening agent, a disintegrant, a flow aid, a lubricant, an adjuvant, a colorant, a diluent, a moistening agent, a preservative, a parietal cell activator, an anti-foaming agent, an antioxidant, a chelating agent, an antifungal agent, an antibacterial agent, an isotonic agent, and mixtures thereof.

Claim 201. (Previously Presented) The composition of claim 191, further comprising at least one additional buffering agent selected from the group consisting of calcium buffering agents, magnesium buffering agents, aluminum buffering agents, sodium buffering agents, bicarbonate salts of a Group IA metal, alkali earth metal buffering agents, and mixtures thereof.

Claim 202. (Currently Amended) The composition of claim 191, further comprising at least one additional buffering agent selected from the group consisting of potassium bicarbonate, magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, magnesium silicate, magnesium citrate, aluminum hydroxide, aluminum hydroxide/magnesium carbonate, potassium carbonate, potassium citrate, ~~aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum glycinate,~~ aluminum magnesium hydroxide, sodium citrate, sodium tartrate, sodium acetate, sodium carbonate, sodium polyphosphate, potassium polyphosphate, sodium pyrophosphate, potassium pyrophosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium phosphate, tripotassium phosphate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium hydroxide, calcium lactate, calcium carbonate, calcium gluconate, calcium bicarbonate, calcium citrate, potassium phosphate, sodium phosphate, and mixtures thereof.

Claim 203. (Canceled)

Claim 204. (Previously Presented) The composition of claim 191, wherein the sodium bicarbonate is present in the composition in a total amount of about 250 mg to about 4000 mg.

Claim 205. (Previously Presented) The composition of claim 191, wherein the sodium bicarbonate is present in the composition in a total amount of about 4 mEq to about 100 mEq.

Claim 206. (Previously Presented) The composition of claim 191, wherein the sodium bicarbonate is present in the composition in a total amount of about 4 mEq to about 30 mEq.

Claim 207. (Previously Presented) The composition of claim 191, wherein the sodium bicarbonate is present in the composition in a total amount of about 10 mEq to about 70 mEq.

Claim 208. (Previously Presented) The composition of claim 191, wherein the sodium bicarbonate is present in the composition in a total amount of about 7 mEq and about 25 mEq.

Claim 209. (Previously Presented) The composition of claim 191, wherein the sodium bicarbonate is present in the composition in a total amount of about 10 mEq.

Claim 210. (Previously Presented) The composition of claim 191, wherein the sodium bicarbonate is present in the composition in a total amount of about 20 mEq.

Claim 211. (Previously Presented) The composition of claim 191, wherein the sodium bicarbonate is present in the composition in a total amount of about 40 mEq.

Claim 212. (Previously Presented) The composition of claim 191, wherein the omeprazole is present in the composition in an amount of about 20 mg.

Claim 213. (Previously Presented) The composition of claim 191, wherein the omeprazole is present in the composition in an amount of about 40 mg.

Claim 214. (Previously Presented) The composition of claim 191, wherein the omeprazole is present in the composition in an amount of about 10 mg to about 100 mg.

Claim 215. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average T_{\max} within about 1 hour after administration.

Claim 216. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average T_{\max} within about 30 minutes after administration.

Claim 217. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average T_{\max} within about 45 minutes after administration.

Claim 218. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average T_{\max} of between about 15 minutes to about 1 hour after administration.

Claim 219. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mgs to a group of fasted adult human subjects, the subjects exhibit an average C_{\max} of the omeprazole of between about 1.0 $\mu\text{g/ml}$ to about 1.7 $\mu\text{g/ml}$.

Claim 220. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average C_{\max} of the omeprazole of between about 0.3 $\mu\text{g/ml}$ to about 1.7 $\mu\text{g/ml}$ after administration.

Claim 221. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition in an omeprazole dosage amount of 40 mg to a group of fasted adult human subjects the subjects exhibit an average C_{\max} of the omeprazole between about 1.0 $\mu\text{g/ml}$ and 1.7 $\mu\text{g/ml}$ at any time within about 60 minutes after administration.

Claim 222. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average C_{\max} of the omeprazole of between about 0.3 $\mu\text{g/ml}$ and 1.7 $\mu\text{g/ml}$ at any time within about 60 minutes after administration.

Claim 223. (Currently Amended) The composition of claim 151, wherein the solid dosage form [[unit]] is a chewable tablet and upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of between about 0.5 $\mu\text{g/ml}$ to 1.7 $\mu\text{g/ml}$ at any time within about 15 minutes after administration.

Claim 224. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of between about 0.7 $\mu\text{g/ml}$ to about 1.7 $\mu\text{g/ml}$ at any time within about 30 minutes after administration.

Claim 225. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit

an average plasma concentration of the omeprazole greater than about 1.0 µg/ml at any time within about 30 minutes after administration.

Claim 226. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole of between about 0.3 µg/ml to 1.7 µg/ml at any time within about 30 minutes after administration.

Claim 227. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole greater than about 1.0 µg/ml at any time within about 40 minutes after administration.

Claim 228. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mgs to a group of fasted adult human subjects, the average plasma concentration of the omeprazole is determined from about 10 subjects.

Claim 229. (Previously Presented) The composition of claim 151, wherein upon oral administration of the composition in an omeprazole dosage amount of about 40 mgs to a group of fasted adult human subjects, the average plasma concentration of the omeprazole is determined from about 10 subjects and is between about 0.7 µg/ml and 1.7 µg/ml at any time within about 30 minutes after administration.

Claim 230. (Currently Amended) The composition of claim 151, wherein the solid dosage form [[unit]] is a chewable tablet and upon oral administration of the composition to a group of fasted adult human subjects, the average plasma concentration of the omeprazole is determined from about 10 subjects and is at least about 0.6 µg/ml at any time within about 15 minutes after administration.

Claim 231. (Previously Presented) The composition of claim 191, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average T_{\max} within about 45 minutes after administration.

Claim 232. (Previously Presented) The composition of claim 191, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average T_{\max} of between about 15 minutes to about 1 hour after administration.

Claim 233. (Previously Presented) The composition of claim 191, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average C_{\max} of the omeprazole of between about 0.3 $\mu\text{g/ml}$ and 1.7 $\mu\text{g/ml}$ at any time within about 30 minutes after administration.

Claim 234. (Previously Presented) The composition of claim 191, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole greater than about 1.0 $\mu\text{g/ml}$ at any time within about 30 minutes after administration.

Claim 235. (Previously Presented) The composition of claim 191, wherein upon oral administration of the composition to a group of fasted adult human subjects, the subjects exhibit an average plasma concentration of the omeprazole greater than about 1.0 $\mu\text{g/ml}$ at any time within about 40 minutes after administration.

Claim 236. (Previously Presented) The composition of claim 191, wherein upon oral administration of the composition to a group of fasted adult human subjects, the average plasma concentration of the omeprazole is determined from about 10 subjects.